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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/759,160
Filing Date: January 20, 2004
Appellant(s): KOHLHASE ET AL.

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Reg. No. 50,417
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 16, 2008 appealing from the Office action mailed April 16, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6558680	Riedel et al.	5-2003
6486106	Charlton et al.	11-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 78-136 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Riedel et al. (U.S. 6,558,680 B1) in view of Charlton et al. (U.S. 6,486,106 B1).

Riedel et al. teach cosmetic or dermatological compositions containing fatty acids, fatty alcohols, non-polar lipids and ethoxylated fatty acid esters (see abstract). In addition, Riedel teaches that such composition can comprise auxiliaries and/or additives such as surfactants (i.e. laureth-4, instant claims 78, 85, 102, 108, 125, and 134; see column 9, line 15, and lines 17- 38; column 11, lines 14-24), and other usual constituents of cosmetic or dermatological formulations, such as polymers (see column 11, lines 14-24). Riedel also teaches that such a composition can also comprise emulsifiers such as acrylate/C10_30-alkyl acrylate cross polymer which is conventionally known in the art as an associative polymer (see column 8, lines 58-59, which meets the limitations of instant claims 78-79, 98-99, 120, and 130-131), cetyl

dimethicone (i.e. trade name Abil Wax 9840) conventionally known in the art as a siloxane elastomer (see table 1, which meets the limitations of instant claims 78-79, 120, and 132-133), PEG-40 hydrogenated castor oil conventionally known in the art as a solubilizer (see column 9, line 5, which meets the limitations of instant claims 115-116), mixtures of emulsifiers containing PEG 30 stearate, or PEG 40 stearate or PEG 100 stearate (instant claims 84, 102, 124, and 134; see col. 9, lines 13 and 18) and ethanol (see column 6, line 65) and further teaches that the composition can be formulated as a skin protection cream, cleansing milk, sunscreen lotion or as a decorative cosmetic (see column 10, lines 1-7, which meets the limitation of claims 78-79 and 120). Moreover, Riedel teaches the use of both amphiphilic polymers (i.e. polyglycerol 3-dihydroxystearate, also known in the art as Cremophor) and associative polymers such as acrylate/C10-30 alkyl acrylate cross polymer in his compositions (see col. 8, lines37-65). Importantly, the composition of Riedel et al. specifically disclose the fatty acids stearic and palmitic (instant claims 80, 86, 102-103, 121, 126, and 134-135) as a preferred embodiment of the invention including the use of the fatty alcohol cetearyl alcohol and the silicone oil cyclomethicone (instant claims 78-79, 81, 87, 102-103, 110, 113, 120, 122, and 134-135; see example 8).

Riedel et al. do not teach the specific amphiphilic polymer, acrylate/vinyl isodecanoate crossprolymer, recited in claims 82, 88, 102-103, 123, 128, and 134-135). Similarly, Riedel et al. do not specifically teach a skin care composition entailing the

addition of component (IV) of at least one of sodium hydroxide and potassium hydroxide.

Charlton et al. teach a skin wash composition (i.e. dermatological composition) containing 0.1-0.5% stabilizing agents such as the amphiphilic polymer Stabylen 30 (or acrylate/vinyl isodecanoate crossprolymer; instant claims 82, 88, 102-103, 123, 128, and 134-135; see col. 4, lines). Charlton et al. further teach the addition of 2-5% PEG 150 distearate or PEG 55 propylene glycol oleate as thickeners (see col. 4, lines 41-49) in the skin wash composition. Charlton et al., also teach the use of neutralizing agents such as sodium hydroxide to neutralize the composition and control the pH of the composition (see column 3, lines 1-12, which meets the limitations of instant claims 78-79, 83, 89, 102-105, 120, and 134-136).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to add sodium hydroxide in order to neutralize the instant cosmetic and dermatological composition of Riedel in view of the fact that such composition may necessitate pH control as disclosed by Charlton et al. Given that Riedel teach a cosmetic and dermatological composition of fatty acids, fatty alcohol, ethoxylated esters, surfactant (such as laureth-2), and non-polar lipids, and Charlton et al. disclose that sodium hydroxide can be used as a neutralizing agent, one of ordinary skill would have been motivated to add the sodium hydroxide of Chapin* to the composition of Riedel with the expectation of adjusting the pH level of the composition in the absence

of evidence to the contrary. Thus, claims 78-79, 83, 89, 102-105, 120, and 134-136 are prima facie obvious over the teachings of Riedel in view of Chapin*.

Similarly, it would have been obvious to one of ordinary skill to incorporate Stabylen 30 and PEG 150 distearate or PEG 55 propylene glycol oleate since Charlton et al. teaches the inclusion of both Stabylen 30 as a stabilizer (i.e. amphiphilic polymer) along with PEG 55 propylene glycol oleate (or PEG 150 distearate) as stabilizers in his dermatological composition. Given that Riedel teaches a cosmetic and dermatological composition of fatty acids, fatty alcohol, ethoxylated esters, surfactant (such as laureth-2), and non-polar lipids, and Charlton et al. teach the inclusion of both amphiphilic polymers and associative polymers in dermatological compositions, and given that Chapin* disclose that sodium hydroxide can be used as a neutralizing agent, one of ordinary skill would have been motivated to incorporate the amphiphilic and associative polymers for stabilizing and thickening purposes as disclosed by Charlton et al. and neutralize the composition of Riedel et al. with sodium hydroxide with the reasonable expectation of providing a stable dermatological composition.

Regarding the term "substantially free" recited in claim 120, it is considered as a broad term. In view of the lack of guidance in the specification and given that applicant did not point out the critical limitation encompassed by the term, Examiner is interpreting the term to mean that a range of 0.2-10% mono- and di-fatty acid esters of glycerol and glycol in a composition necessarily suggest that such composition is substantially free of such fatty acid esters.

Moreover, while the exact percentage of the ingredients are not disclosed by Riedel, it is generally noted that differences in concentration, ranges or percentages do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454,456, 105 USPQ 233, 235 (CCPA 1955). Given that applicant did not point out the criticality of specific ranges or percentages of the invention, it is concluded that the normal desire of scientists or artisans to improve upon what is already generally known would provide the motivation to determine where in a disclosed set of percentage or ranges is the optimum combination of percentages.

Regarding the saponification of the fatty acids as recited in claims 106-107, it is considered that one of ordinary skill in the art at the time of the invention was made would found it obvious to conclude that the composition of Riedel would possess the same percentage of saponified fatty acids as that disclosed by the applicant given that these compositions both entail the same ingredients, therefore, it would be expected that these ingredients would not lead to no more than 9% of saponified fatty acid acids.

*Please note that the Examiner inadvertently entered Chapin instead of Charlton in the conclusionary statement of the Final 103 (a) rejection. However the Charlton reference was correctly entered under the 103(a) statute and clearly cited for his teachings.

It is further noted that In re Best,195 USPQ 430, and In re Fitz.gerald~ 205 USPQ 594, discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

(10) Response to Argument

(1) Appellants submit that due to the fundamental differences between the compositions of RIEDEL and the compositions of CHARLTON there is no motivation for one of ordinary skill in the art to combine the teachings of RIEDEL and CHARLTON.

The Examiner disagrees because Riedel teaches cosmetic and dermatological compositions containing fatty acids, fatty alcohols, non-polar lipids, emulsifiers, and ethoxylated fatty acid esters (see abstract). Charlton teaches skin wash compositions which are also dermatological compositions and which also contain emulsifiers, stabilizing agents, along with an alpha hydroxy active agent (see abstract and col. 4). Importantly, Charlton teaches addition of other components such as neutralizing agents in order to control the pH of the composition; skin conditioning and soothing agents for skin conditioning purposes, etc...(see col. 3, lines 1-25). Moreover, Riedel teaches addition of customary auxiliaries and excipients to the composition including α-hydroxy acids as antioxidants (see col. 11, lines 57-60). Furthermore, the examples of Riedel clearly teaches adjustment of the pH in his composition further proffering support as to

why one of ordinary skill would add additional components such as neutralizing agents to the composition of Riedel (see col. 9, lines 47-54 and col. 9, lines 47-54). Thus, it is the Examiner contention that given that Riedel teaches dermatological compositions and suggests addition of customary additives to his compositions, and given that Charlton also teaches dermatological compositions, one of ordinary skill in the art would have indeed be motivated to add any components of Charlton into the composition Riedel since both composition are used for the same skin care purposes. Regardless of the property being imparted by Reidel as compared to Charlton, the Examiner contends that one of ordinary skill in the art would have the motivation to add any component of Charlton into the composition of Riedel since both compositions are comparable and used for the same purpose.

(2) RIEDEL in view of CHARLTON does not render it obvious adding sodium and/or potassium hydroxide to the compositions of RIEDEL.

As stated in the Non-Final Office Action dated 10/01/07 and the Final Office Action dated 04/16/08, the Examiner clearly stated on the record that Riedel does not teach addition of potassium hydroxide or sodium hydroxide to his composition. Charlton, on the other hand, who also teach dermatological compositions suggest addition of neutralizing agents such as sodium hydroxide to his skin composition due to the presence of α-hydroxy acid and certain surfactants. As previously stated, Riedel teaches addition of acidic components in his composition including addition of α-hydroxy acids as antioxidants, active agents such as acetylsalicylic acid, and addition of stearic

and palmitic acid which are all acidic components (see col. 4, lines 35-36; col. 11, lines 57-59; and col. 14, lines 5-16). Moreover, in all of the examples of Riedel, the pH of the composition is adjusted to a neutral pH further supporting the notion that neutralizing agents can be added to the composition. Consequently, in view of Charlton who teaches addition of neutralizing agents such as sodium hydroxide to control the pH of acidic-containing compositions and in light of the various acidic components found in the compositions of Riedel and the pH adjustment taught in Riedel's examples, one of ordinary skill in the art would have indeed found it obvious to add sodium hydroxide in order to control the pH of the composition of Riedel.

> (3) Appellants submit that the compositions of RIEDEL are different from the claimed compositions for at least the reason that they do not contain sodium and/or potassium hydroxide. Moreover, even if one were to assume, arguendo, that one of ordinary skill in the art would be motivated to combine the teachings of RIEDEL and CHARLTON and, in view thereof, would add a neutralizing agent and in particular, sodium and/or potassium hydroxide to the compositions of RIEDEL (as explained above, both assumptions are without basis), this addition would not necessarily and automatically result in a pearlescent composition.

The Examiner disagrees as the pearlescent effect is due to the components in the composition. In fact, applicant's own specification teaches that emulsions from the prior art have a pearlescent effect due to the presence of mono and di-fatty acid ester of glycerol or glycol such as glycerol stearates, laurates, or myristate and sodium and potassium hydroxide (see Applicant's specification, pg. 1, lines 27-33 and pg. 2, lines 1-25; Riedel, col. 4, lines 54-64); all of which are taught as ingredients in the compositions of Riedel. Moreover, the Examiner contends that addition of pearlescent pigments such

as titanium dioxide is well known in the art to cause pearlescent effect and Riedel teaches addition of such pigments in the composition (see Riedel, col. 11, lines 5-13). Consequently, the Examiner asserted that in light of the specification and the ingredients found in the compositions of Riedel with overlapping ratios and concentrations as those disclosed by the instant application, such compositions would necessarily be pearlescent since properties are inseparable from the compounds.

> (4) Independent claim 120 and dependent claim 119 (dependent from claim 78) both recite, inter alia, that the cosmetic or dermatological composition is substantially free of mono- and di-fatty acid esters of glycerol and glycol. In contrast, RIEDEL teaches that the compositions disclosed therein comprise from 0.2 to 10 % by weight of fatty acid mono- and diglycerides (see, e.g., abstract of RIEDEL). The lowest concentration of a corresponding compound (glyceryl stearate) used in the Examples of RIEDEL is 2.00 % by weight (see Example 1). Accordingly, RIEDEL not only fails to render obvious the subject matter of claims 119 and 120 but even teaches away therefrom. CHARLTON is apparently unable to cure this deficiency of RIEDEL, and neither has the Examiner made any allegations in this regard.

The Examiner disagrees given that the term "substantially free" is a broad term and given that applicant did not provide any clear definition or critical limitation. As a result, the Examiner interpreted Riedel's incorporation of the range of 0.2%-10% as being substantially free of the aforementioned fatty acids. In fact, Webster's Ninth New Collegiate Dictionary defines the term "substantially" as largely but not wholly that which is specified. In other words, substantially free does not mean absolutely free, therefore Riedel's inclusion of at least 0.2% of mono- and di-fatty acid esters of glycerol and glycol is considered to be "substantially free" in this instance. Thus, the Examiner concludes that a *prima facie case* of obviousness was indeed established.

(5) Appellants submit that even if one were to assume, arguendo, that one of ordinary skill in the art would be motivated to combine the teachings of RIEDEL and CHARLTON it is not seen that he or she would have any apparent reason to incorporate one or more of acrylate/vinyl isodecanoate crosspolymer, PEG-55 propylene glycol oleate and PEG-150 distearate, i.e., polymers which are disclosed in CHARLTON as optional components of the compositions disclosed therein, into the compositions of RIEDEL.

The Examiner disagrees given that Riedel clearly teaches addition of customary auxiliaries and additives including polymers to his dermatological compositions (see col. 11, lines 14-24). While Riedel was silent as to the type of polymers to be included into the compositions, Charlton teaches addition of polymers as thickeners or as stabilizers into dermatological compositions (see col. 4). As for applicant's arguments that acrylate/vinyl isodecanoate crosspolymer (i.e. Stabylen 30) is only added as a result of urethane polymers that are present in the composition, the Examiner contends that Riedel teaches addition of all polymers which would not exclude urethane polymers. Thus, one of ordinary skill in the art would reasonably be motivated to include urethane polymers along with Stabylen 30 into the dermatological composition of Riedel if the desire was to increase deposition of active ingredients on and in the upper layers of the skin as taught by Charlton del (see Charlton, col. 3, lines 26-36). Moreover, the Examiner would like to reiterate the fact that Riedel clearly taught addition of surfactants, stabilizers, and emulsifiers all of which are well-known in the art as stabilizing agents. Thus, appellants' conclusion that addition of Stabylen 30 would only be advantageous only if a polyurethane is included in the composition of Riedel is fallible.

(6) Appellants respectfully disagree with the Examiner in this regard. Specifically, page 11 of the present specification states, inter alia (emphasis added):
Siloxane elastomers are partially or completely crosslinked and in most cases have a three-dimensional structure. They are obtainable by a reaction of vinyl-terminated polymethylsiloxane and methylhydrodimenthylsiloxane or else by reaction of hydroxy-terminated dimethylpolysiloxane and trimethylsiloxy-terminated methylpolysiloxane:

The Examiner disagrees with Appellant in regard to the definition of a siloxane elastomer. First the Examiner contends that Abil Wax 9840 as taught by Evonik Industries Data Sheet is an organopolysiloxane synthesized by linking (i.e. crosslinking) polydimethylsiloxane with long hydrocarbon chains which would necessarily suggest that Abil Wax 9840 is a siloxane elastomer. Second, Appellant's specification further stated that in most cases (i.e. not in all cases) such elastomer may take a three-dimensional form. However, it is the Examiner's position that a non-three dimensional siloxane elastomer would necessarily still be considered a siloxane elastomer as a three dimensional structure is not a requisite for being a siloxane elastomer according to the specification. Furthermore, the specification teaches that siloxane elastomers are obtainable by a reaction of a vinyl terminated siloxane; however, such language does not preclude other possible ways of obtaining siloxane elastomers. Consequently, the Examiner contends that Appellant is arguing a much narrow view of the definition of a siloxane elastomer. Thus, the Examiner asserts that in light of the broad interpretation of what constitute a siloxane elastomer, a prima facie case of obviousness was in fact established.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/SREENI PADMANABHAN/

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